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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,683	08/28/2003	Imants Lauks	PAT 927-2 US	5656
26123 7590 12/26/2007 BORDEN LADNER GERVAIS LLP Anne Kinsman WORLD EXCHANGE PLAZA 100 QUEEN STREET SUITE 1100 OTTAWA, ON K1P 1J9 CANADA			EXAMINER NAGPAUL, JYOTI	
			ART UNIT 1797	PAPER NUMBER
			NOTIFICATION DATE 12/26/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/649,683

Applicant(s)

LAUKS ET AL.

Examiner

Jyoti Nagpaul

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,10-12 and 17-25 is/are rejected.
- 7) ☒ Claim(s) 3-9,13-16 and 26-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on April 18, 2007 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 13** recites the limitation "the injector pump" in Line 3. There is insufficient antecedent basis for this limitation in the claim.
4. **Claims 24-27** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are:

With respect to Claim 24, applicants' recite, "for supplying liquid to a vented air chamber", applicants' are claiming an apparatus; it is unclear in the recited claim as to what the structural element is creating this vented air chamber. Clarification is needed.

With respect to Claim 25, applicants' recite, "for supplying liquid to an enclosed air chamber at the fluid receiving location", applicants' are claiming an apparatus, , it is unclear in the recited claim as to what the structural element is creating an enclosed air chamber. Clarification is needed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 21 and 24-25** are rejected under 35 U.S.C. 102(b) as being anticipated by Stiene (WO 02/49507).

As for Claim 1, Stiene teaches an apparatus for measuring certain properties of a fluid. The apparatus comprises an initially dry fluidic path (4) having a fluid application end (7) for accepting fluid and an effluent end, for example the location where the fluid stops where the hydrophobic gate is in Figure 6c, for delivering to the receiving location, see Figure 6e. Stiene further teaches an isolator/hydrophobic gate for fluidically isolating the effluent end from the receiving location when the fluidic path includes a fluid. Stiene further teaches driving means/electrodes for osmotically pumping fluid out of the effluent end of the fluidic path element and across the isolator to the fluid receiving location. (See Figures 6c-6e) Stiene further teaches a sealing element/laminate for sealing the fluidic path along a perimeter thereof to prevent fluid flow from the fluidic path/channel at the perimeter during electro-osmotic pumping. (For example, see pg 27, Lines 13-18 and pg 29 Lines 25-34)

As for Claim 21, Stiene fails to teach the electro-osmotically pumped fluid has an electrolyte concentration of less than 10 milimolar. However, applicants' are claiming an apparatus. It is fundamental that an apparatus claim defines the structure of the invention and not how the structure is used in a process or what *material* the structure houses in carrying out the process. (See Ex parte Masham) As long as the device of Stiene is capable of electro-osmotically pumping fluid that has an electrolyte

concentration of less than 10 milimolar, then the prior art meets the requirements of the claimed feature.

As for claims 24 and 25, as well as the claim is understood, it appears that Stiene supplies fluid to a vented air chamber at the fluid receiving location and to an enclosed air chamber at the fluid receiving location.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 2, 10-12, 19-20 and 22-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiene in view of Paul (US 6013164).

Refer above for the teachings of Stiene.

As for claim 2, Stiene fails to teach the initially dry fluidic path is made up of a micro-porous material.

Paul teaches an apparatus for pumping and manipulating fluid flow in packed capillary based systems. Paul discloses at least one capillary channel forming a fluid passageway and having a porous dielectric medium disposed therein to cause an electrolyte to move in the microchannel and increase fluid flow control through the system. (See Col. 1, Lines 58-68) (See Col. 2, Lines 1-10) Paul further

It would have been obvious to one having ordinary skill in the art to provide the initially dry fluidic path of Stiene with a micro-porous material to achieve the predictable results of increasing fluid control through the system.

As for claims 10 and 11, Stiene fails to teach the fluidic path contains a mobilizable reagent selected from the group of luminogenic, fluorigenic, electrogenic and chemoluminescent substrates and combinations thereof. However, applicants' are claiming an apparatus. It is fundamental that an apparatus claim defines the structure of the invention and not how the structure is used in a process or what material the structure houses in carrying out the process. (See Ex parte Masham) As long as the

fluidic path of Stiene and Paul are capable of containing a mobilizable reagent, the prior art meets the requirements of the claimed feature.

Additionally, it would have been obvious to one having ordinary skill in the art to provide the fluidic path of Paul with a mobilizable reagent selected from the group of luminogenic, flurogenic, electrogenic and chemolumiescent substrates and combinations thereof to achieve the predictable results of versatility in detection of the sample.

As for claims 19 and 20, Stiene and Paul fails to teach the micro-porous fluidic path has pores less than 0.2 micrometer radius. Paul teaches micro-porous fluidic path. It would have been obvious to one having ordinary skill in the art to provide the device of Stiene and Paul with a micro-porous fluidic path having pores less than 0.2 micrometer radius to achieve the predictable results of obtaining the analyte of interest and thus increasing the efficiency of the overall process.

As for Claims 22 and 23, Stiene and Paul fail to teach the fluidic path is trapezoidal shaped with its fluid application end wider than its effluent end. It would have been obvious to one having ordinary skill in the art to provide a fluidic path that is trapezoidal shaped with its fluid application end wider than its effluent end to achieve predictable results of better flow control through the device.

11. **Claims 17 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiene in view of Levy (US 6030582).

Refer above for the teachings of Stiene.

Stiene fails to teach the fluid introduced into the initially dry fluidic path/needle (4) at its application end (7) is from an integral fluid reservoir. Stiene does teach obtaining fluid from the patient's body. It is well known in the art to obtain sample from cuvettes comprising a seal that ruptures from a needle.

Further, Levy teaches an apparatus for obtaining sample from a vessel/integral reservoir (12) from puncturing a seal or septum (18) located on the vessel (12). (See Figure 1-3)

It would have been obvious to one having ordinary skill in the art to obtain fluid from an integral reservoir/vessel as it is known in the art as disclosed by Levy to increase the versatility of the device such as further using the device without the patient having to be there or in a laboratory setting.

Allowable Subject Matter

12. **Claims 3-9, 14-16 and 28** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Prior art fails to teach an air gap adjacent the effluent end.

13. **Claim 13** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Prior art fails to teach or fairly suggest the fluid receiving device includes a first receiving element containing a dry reagent to be mobilized when the receiving device receives fluid from the injector pump

and a second fluid receiving element fluidically connected to the first fluid receiving element for receiving the injected fluid containing the mobilized reagent.

14. **Claims 26-27** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Prior art fails to teach wherein the fluid receiving device is a micro-porous lateral flow strip with a fluid receiving location along its length.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JN


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